



Attorney Docket: 00039.09CON

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Joshua D. Rabinowitz, et al. ) Examiner: M. Haghighatian  
Serial No.: 10/749,535 ) Group Art Unit: 1616  
Filing Date: December 30, 2003 ) Confirmation No.: 8875  
For: DELIVERY OF ERECTILE )  
DYSFUNCTION DRUGS THROUGH AN )  
INHALATION ROUTE )

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESUBMISSION OF INFORMATION DISCLOSURE STATEMENT AND FORM 1449  
OR IN THE ALTERNATIVE PETITION UNDER 37 C.F.R. §1.182 TO RESUBMIT  
INFORMATION DISCLOSURE STATEMENT**

The Information Disclosure Statement and Form 1449s previously submitted on September 24, 2004 are resubmitted for the above referenced case, or in the alternative, Applicants respectfully petition to resubmit the attached Information Disclosure Statement and Form 1449s previously submitted in the above-captioned patent application.

**STATEMENT OF FACTS**

The above-captioned application was filed on December 30, 2003. On September 24, 2004, Applicant submitted the attached Information Disclosure Statement and Form 1449s in connection with the above-referenced application. Enclosed is a copy of the date-stamped return receipt postcard indicating the OIPE received the Information Disclosure Statement and Form 1449s on September 24, 2004.

As a customary practice by our office and in a thorough review of our file prior to the issue fee due date of July 5, 2006, Applicant realized that the initialed Form 1449s described

37 CFR 1.8

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 5, 2006.

Signature: Veronica Doucet

Name: Veronica Doucet

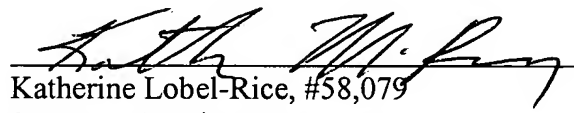
above had not been returned. After a telephone conversation with the Examiner on May 16, 2006, Applicant was instructed to resubmit the Information Disclosure Statement and Form 1449s with the submission of the Issue Fee payment.

On the basis of the foregoing, Applicant respectfully requests that the Information Disclosure Statement and Form 1449s be resubmitted and made part of the application record as discussed above. Applicant respectfully requests the Examiner issue a Supplemental Notice of Allowance including the initialed Form 1449s.

Applicant believes that no fees are due at this time. However, if in the alternative, a Petition is necessary, Applicant hereby authorizes the Petition fee in the amount of \$130.00 to be charged to deposit account No. 19-5117. The undersigned hereby authorizes the charge of any required fees not included or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

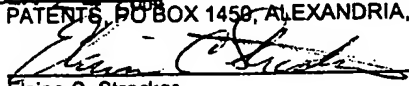
Date: July 5, 2006

  
Katherine Lobel-Rice, #58,079  
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S:\CLIENTFOLDERS\ALEXZA\39.09CON\00039.09CON PETITION FOR IDS.DOC

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS PAPER AND THE DOCUMENTS REFERRED AS BEING ATTACHED OR ENCLOSED HERewith ARE BEING DEPOSITED WITH THE UNITED STATES POSTAL OFFICE ON SEP 24 2004 AS EXPRESS MAIL ADDRESSED TO: MAIL STOP AMENDMENT COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450

  
Elaine C. Stracker



PATENT  
Attorney's Docket No.: 00039.09CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.  
Serial No.: 10/749,535  
Filed: 12/30/2003  
Title: DELIVERY OF ERECTILE DYSFUNCTION DRUGS THROUGH AN INHALATION ROUTE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:


In accordance with their continuing duty of disclosure under 37 CFR §§ 1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

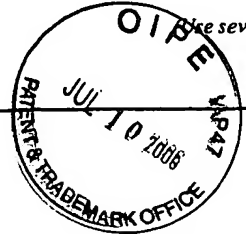
In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including any extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 502731. Please direct all correspondence to the following customer number.

Respectfully submitted,

Date: SEP. 24 2004

  
Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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TEL: (650) 687-3905  
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<b>Form PTO-1449</b> <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> 	Docket Number: 00039.09 CON	Application Number: 10/749,535
	Applicant: Joshua D. RABINOWITZ et al.	
	Filing Date: 12/30/2003	Group Art Unit: Not Yet Known

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	02/02/1971	3,560,607	Hartley et al.			
	2.	05/27/1980	Re. 30,285	Babington			
	3.	01/23/1990	4,895,719	Radhakrishnun et al.			
	4.	09/17/1991	5,049,389	Radhakrishnun			
	5.	02/14/1995	5,388,574	Ingebretsen			
	6.	08/13/1996	5,544,646	Lloyd et al.			
	7.	12/09/1997	5,694,919	Rubsamen et al.			
	8.	04/07/1998	5,735,263	Rubsamen et al.			
	9.	04/14/1998	5,738,865	Baichwal et al.			
	10.	06/02/1998	5,758,637	Ivri et al.			
	11.	06/29/1999	5,915,378	Lloyd et al.			
	12.	08/10/1999	5,934,272	Lloyd et al.			
	13.	09/28/1999	5,957,124	Lloyd et al.			
	14.	10/05/1999	5,960,792	Lloyd et al.			
	15.	11/30/1999	5,993,805	Sutton et al.			
	16.	03/28/2000	6,041,777	Faithfull et al.			
	17.	04/18/2000	6,051,566	Bianco			
	18.	08/01/2000	6,095,153	Kessler et al.			
	19.	08/15/2000	6,102,036	Slutsky, et al.			
	20.	06/05/2001	6,241,969	Saidi et al.			
	21.	07/03/2001	6,255,334	Sands			
	22.	01/14/2003	6,506,762	Horvath et al.			
	23.	02/04/2003	6,514,482	Bartus et al.			
	24.	07/15/2003	6,591,839	Meyer et al.			
	25.	09/06/2001	US 2001/0020147	Staniforth et al.			
	26.	03/28/2002	US 2002/0037828	Wilson et al.			

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

Docket Number: 00039.09 CON

Application Number: 10/749,535

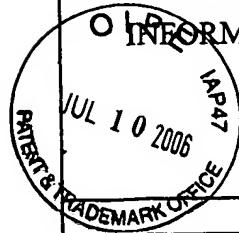
Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/30/2003

Group Art Unit: Not Yet Known

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)



27.	05/16/2002	US 2002/0058009	Bartus et al.			
28.	07/04/2002	US 2002/0086852	Cantor			
29.	08/22/2002	US 2002/0112723	Schuster et al.			
30.	11/28/2002	US 2002/0176841	Barker et al.			
31.	01/02/2003	US 2003/0004142	Prior et al.			
32.	02/13/2003	US2003/0032638	Kim et al.			

## RELATED ALEXZA MOLECULAR DELIVERY CORPORATION PATENT DOCUMENTS

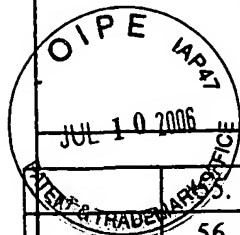
33.	08/04/2003	10/633,876	Hale et al.			
34.	08/04/2003	10/633,877	Hale et al.			
35.	12/30/2003	10/749,537	Rabinowitz et al.			
36.	12/30/2003	10/749,539	Rabinowitz et al.			
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46.	01/29/2004	10/768,281	Rabinowitz et al.			
47.	01/29/2004	10/768,293	Rabinowitz et al.			
48.	01/30/2004	10/769,046	Rabinowitz et al.			
49.	01/30/2004	10/769,051	Rabinowitz et al.			
50.	01/29/2004	10/769,157	Rabinowitz et al.			
51.	01/29/2004	10/769,197	Rabinowitz et al.			
52.	02/09/2004	10/775,583	Rabinowitz et al.			
53.	02/09/2004	10/775,586	Rabinowitz et al.			
54.	03/03/2004	10/791,915	Hale et al.			

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<b>Form PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	Docket Number: 00039.09 CON	Application Number: 10/749,535
	Applicant: Joshua D. RABINOWITZ et al.	
	Filing Date: 12/30/2003	Group Art Unit: Not Yet Known



55.	03/03/2004	10/792,001	Rabinowitz et al.			
56.	03/03/2004	10/792,012	Hale et al.			
57.	03/03/2004	10/792,013	Rabinowitz et al.			
58.	03/03/2004	10/792,096	Hale et al.			
59.	03/03/2004	10/792,239	Hale et al.			
60.	03/31/2004	10/813,721	Rabinowitz et al.			
61.	03/31/2004	10/813,722	Rabinowitz et al.			
62.	03/31/2004	10/814,690	Rabinowitz et al.			
63.	03/31/2004	10/814,998	Rabinowitz et al.			
64.	04/01/2004	10/815,527	Rabinowitz et al.			
65.	04/01/2004	10/816,407	Rabinowitz et al.			
66.	04/01/2004	10/816,492	Rabinowitz et al.			
67.	04/01/2004	10/816,567	Rabinowitz et al.			
68.	08/04/2004	10/912,462	Hale et al.			
69.	01/23/2003	US 2003/0015196	Hodges et al.			
70.	04/03/2003	US 2003/0062042	Wensley et al.			
71.	11/13/2003	US 2003/0209240	Hale et al.			
72.	01/02/2003	US 2003/0000518	Rabinowitz et al.			
73.	01/09/2003	US 2003/0005924	Rabinowitz et al.			
74.	01/09/2003	US 2003/0005925	Hale et al.			
75.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
76.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
77.	01/16/2003	US 2003/0012737	Rabinowitz et al.			
78.	01/16/2003	US 2003/0012738	Rabinowitz et al.			
79.	1/16/2003	US 2003/0012740	Rabinowitz et al.			
80.	01/23/2003	US 2003/0015189	Rabinowitz et al.			
81.	01/23/2003	US 2003/0015190	Rabinowitz et al.			
82.	01/23/2003	US 2003/0017114	Rabinowitz et al.			
83.	01/23/2003	US 2003/0017115	Rabinowitz et al.			
84.	01/23/2003	US 2003/0017116	Rabinowitz et al.			

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Form PTO-1449

Docket Number: 00039.09 CON

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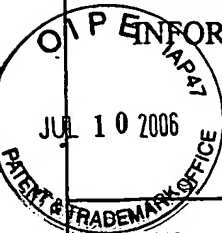
INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/30/2003

Group Art Unit: Not Yet Known



	85.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
	86.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
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	89.	1/30/2003	US 2003/0021753	Rabinowitz et al.			
	90.	01/30/2003	US 2003/0021754	Rabinowitz et al.			
	91.	01/30/2003	US 2003/0021755	Hale et al.			
	92.	02/20/2003	US 2003/0035776	Hodges et al.			
	93.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
	94.	05/27/2004	US 2004/010148	Hale et al.			
	95.	07/31/2003	US 2003/0138382	Rabinowitz			
	96.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
	97.	01/15/2004	US 2004/0009128	Rabinowitz et al.			
	98.	05/20/2004	US 2004/0096402	Hodges et al.			
	99.	05/27/2004	US 2004/0099269	Hale et al.			
	100.	06/03/2004	US 2004/0105818	Hale et al.			
	101.	06/03/2004	US 2004/0105819	Hale et al.			
	102.	07/01/2004	US 2004/0126326	Rabinowitz et al.			
	103.	07/01/2004	US 2004/0126327	Rabinowitz et al.			
	104.	07/01/2004	US 2004/0126328	Rabinowitz et al.			
	105.	07/01/2004	US 2004/0126329	Rabinowitz et al.			
	106.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
	107.	07/01/2004	US 2004/0127490	Rabinowitz et al.			
	108.	08/12/2004	US 2004/0156789	Rabinowitz et al.			
	109.	8/12/2004	US 2004/0156790	Rabinowitz et al.			
	110.	08/12/2004	US 2004/0156791	Rabinowitz et al.			

## FOREIGN PATENT DOCUMENTS

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Form PTO/SB/08

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: 00039.09 CON

Application Number: 10/749,535

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/30/2003

Group Art Unit: Not Yet Known

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	111.	03/14/1990	EP 0 358 114	Europe			
	112.	07/03/2001	EP 1 080 720	Europe			
	113.	08/29/2001	EP 0 606 486	Europe			
	114.	04/11/1996	WO 96/09846	WIPO			
	115.	05/09/1996	WO 96/13161	WIPO			
	116.	05/09/1996	WO 96/13290	WIPO			
	117.	05/09/1996	WO 96/13291	WIPO			
	118.	05/09/1996	WO 96/13292	WIPO			
	119.	10/03/1996	WO 96/30068	WIPO			
	120.	08/07/1997	WO 97/27804	WIPO			
	121.	05/28/1998	WO 98/22170	WIPO			
	122.	07/23/1998	WO 98/31346	WIPO			
	123.	08/27/1998	WO 98/36651	WIPO			
	124.	04/08/1999	WO 99/16419	WIPO			
	125.	12/16/1999	WO 99/64094	WIPO			
	126.	01/06/2000	WO 00/00176	WIPO			
	127.	01/06/2000	WO 00/00215	WIPO			
	128.	05/18/2000	WO 00/27363	WIPO			
	129.	05/25/2000	WO 00/29053	WIPO			
	130.	09/17/2000	WO 00/47203	WIPO			
	131.	11/02/2000	WO 00/64940	WIPO			
	132.	11/09/2000	WO 00/66206	WIPO			
	133.	12/21/2000	WO 00/76673	WIPO			
	134.	01/25/2001	WO 01/05459	WIPO			
	135.	03/28/2002	WO 02/24158	WIPO			

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

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DATE CONSIDERED:

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Form PTO-1449

# INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

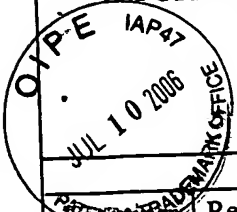
Docket Number: 00039.09 CON

Application Number: 10/749,535

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/30/2003

Group Art Unit: Not Yet Known



Ref. No.	Title
136.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
137.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology</i> (Berl). 102:443-450.
138.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
139.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society.</i> 966-974.
140.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology.</i> 32(5):591-600.
141.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology.</i> 93(3): 619-628.
142.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.
143.	Gonda, I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <i>The Lung: Scientific Foundations.</i> Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.
144.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior.</i> 36(1):1-7.
145.	Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 $\mu\text{m}$ ," <i>J. Aerosol Sci.</i> 17(5):811-822.
146.	Huizer, H., "Analytical studies on illicit heron. V. Efficacy of volatilization during heroin smoking," <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.
147.	Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.
148.	Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics.</i> 279(1):69-76.
149.	Martin, B.R. and Lue, L.P. (May/June 1989). "Pyrolysis and Volatilization of Cocaine," <i>Journal of Analytical Toxicology</i> 13:158-162.
150.	Mattox, A.J. and Carroll, M.E., (1996). "Smoked heroin self-administration in rhesus monkeys," <i>Psychopharmacology</i> , 125:195-201.
151.	Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i> , (1997) 173:201-224.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: 00039.09 CON

Application Number: 10/749,535

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/30/2003

Group Art Unit: Not Yet Known

152. Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," *Drug and Alcohol Dependence*. 53:111-120.
153. Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE"
154. Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," *Environ. Sci. Technol.* 31:2428-2433.
155. Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.
156. Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," *J. Agric. Food Chem.* 47(12):5133-5145.
157. Sekine, H. and Nakahara, Y. (1987). "Abuse of Smoking Methamphetamine Mixed with Tobacco: 1. Inhalation Efficiency and Pyrolysis Products of Methamphetamine," *Journal of Forensic Science* 32(5):1271-1280.
158. Vapotronics, Inc. (1998) located at <http://www.vapotronics.com.au/banner.htm>, 11 pages, (visited on June 5, 2000).
159. Ward, M.E. MD, et al. (December 1997). "Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System," *Clinical Pharmacology & Therapeutics* 62(6):596-609.
160. Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." *Pharmacology Biochemistry & Behavior*. 55(2):237-248.

EXAMINER:

DATE CONSIDERED:

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